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| EXAMINER |
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HENLEY III, RAYMOND J

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|------------------------------------|--|
| Office Action Summary | Application No. 10/735,437 | Applicant(s) OAZI ET AL. | |
| | Examiner Raymond J Henley III | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,6 and 8-18 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 19-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

CLAIMS 1-34 ARE PRESENTED FOR EXAMINATION

Priority

In order to perfect Applicants' claim for domestic priority, page 1 of the specification, before line 1 should be amended to read "This application is a divisional of U.S. Application Serial. No. 10/107,671, filed March 26, 2002, now U.S. Patent No. 6,686,375."

Grammatical Review of Claims

Claims 1-34 should be reviewed for grammatical errors. An example of such error in claim 1 are at line 1, ---an--- should be inserted before "effective" and ---the--- should be inserted before "plant" at line 2.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 7, 20, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "comprising" in claim 2 (line 2), claim 3 (line 2), claim 7 (line 2), claim 20 (line 2), claim 23 (line 2) renders the claimed subject matter indefinite. The expression is employed to set forth the members of a Markush group of elements. Such a group must be definite as to the members included therein. The use of the expression "comprising", however, opens the group for inclusion of other, but non-specified, members. Thus, the metes and bounds of the subject matter for which applicants are seeking patent protection are unclear.

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In claim 2, line 1, the term "solvents" is not consistent with the recitation in claim 1, line 2 of "solvent".

In claim 22, line 1 the term "using" does not make clear any intended steps for accomplishing the objective of treating subjects for developing hepatoprotection. Applicants may wish to consider adopting the same language as employed in claim 1 of their U.S. Patent No. 6,686,375 in order to overcome this point of rejection, i.e., including a step of administering and a subject to whom the composition is administered. In doing so, however, applicants should be aware that such will bring up an issue of statutory double patenting against which a terminal disclaimer will have no effect (note double patenting rejection below).

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Maurya et al. (U.S. Patent No. 6,548,086, cited by the Examiner).

The applied reference has a common assignee and common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was

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derived from the inventors of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Maurya et al. teach pharmaceutical compositions comprising an effective amount of an extract obtained from any part of the plant *Cryptolepis buchanani*, either as such or its individual constituents singly or in composition with each other, optionally associated with pharmaceutically acceptable additives (col. 4, lines 23-30). The additives may be selected from proteins, carbohydrates, sugar, talc, magnesium stearate, cellulose, calcium carbonate, starch-gelatin paste and/or pharmaceutically acceptable carriers, diluents or solvents (col. 4, lines 32-35). As the extracts, Maurya et al. teach the A001 extract and the F001, F002 and F003 fractions thereof (col. 7, line 59 – col. 8, line 5).

The recitation in the present claims that the compositions are useful for hepatoprotection is noted, but is not seen to distinguish over the compositions of the prior art because such a recitation does not impart any material limitation to the claimed compositions that is not found in the prior art compositions.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 21 are rejected under 35 U.S.C. 103(a) as being obvious over Maurya et al., as above.

The applied reference has a common assignee and common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

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The difference between the above and the claimed subject matter lies in that the references fails to teach the presently claimed proportion of ingredients.

However, to the skilled artisan, the claimed subject matter would have been obvious because the determination of the optimum ingredient proportions would have been a matter well within the purview of the skilled artisan and the artisan would have been motivated to do so in order to provide the most effective therapeutic composition possible.

Comments Regarding Claims 5-18

Claims 5-18 are not subject to the above rejections over the Maurya et al. patent because while Maurya et al. teach the majority of preparation steps at col. 10, "Example 1", Maurya et al. is silent as to the collection of the water-soluble fraction F004, which is required by the present claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,686,375. Although the conflicting claims are not identical, they are not patentably distinct from each other because

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in the present claims, i.e., claim 22, the term using would encompass the steps of administration as are present in the patented claims.

As noted above with respect to the rejection of claim 22 under 35 U.S.C. 112, second paragraph, should applicants amend claim 22 to be consistent with that of claim 1 of the '375 patent, a statutory double patenting rejection would be necessitated. Terminal disclaimers have no effect for overcoming such a rejection.


Allowable Subject Matter

Claims 5, 6 and 8-18 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

June 6, 2004